Submission No 120

INQUIRY INTO USE OF CANNABIS FOR MEDICAL PURPOSES

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Andrew Katelaris

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Attention: Merrin Thompson
Medical Cannabis Inquiry
Fax: 9230 2981

Dear Merrin,

Thank you for accepting this submission slightly out of time. An additional submission from the IHA will follow. I can be contacted at

Sincerely

Dr Andrew Katelaris MD

Submission into the use of cannabis for medical purposes, prepared by Dr Andrew Katelaris MD

1. Cannabis species (Cannabis sativa and indica) are amongst humanity's oldest cultivated plants and have found extensive use in many cultures as a source of fibre, food and medicine. A global prohibition against cannabis was initiated in 1938 by corrupt police and legislators, after an extensive misinformation campaign conducted by the Randolf Hearst press.

2. Prior to the prohibition, cannabis, generally in the form of a tincture, was widely used by western doctors to treat a multiplicity of human ills, having been introduced from India by Dr W. B. O'Shaughessy. The therapeutic potential of cannabis was not fully realised at that time due to an incomplete knowledge of the phytochemistry of the cannabis plant and the difficulty of standardising potency and composition of a non–water soluble substance. The American Medical Association of the day made an impassioned plea that the prohibition not include medical cannabis, as they considered it a valued therapeutic.

3. Following the isolation and characterisation of THC (tetrahydocannabinol) by Dr Ralph Mechoulem in Israel, the scientific investigation of the chemistry of the cannabinoids proceeded, although severely curtailed by lack of funding and the restrictive policies of the DEA, an organisation which has trenchantly maintained that cannabis is an addictive substance with no medical application, despite overwhelming evidence to the contrary. Filed in 1972, the first rescheduling petition was denied by the DEA 22 years later, over the objections of their own administrative law judge Francis Young, who said in court records: "Marijuana, in its natural form, is one of the safest therapeutically active substances known to man."

4. Notwithstanding the position adopted by the DEA, the U.S. Food and Drug Administration licensed synthetic THC, in the form of Marinol, to be supplied on prescription. These preparations have been available since the 1970's and have been placed in Schedule III (the same as codeine), while plant cannabis remains in Schedule 1, with extreme restriction. Most medical cannabis patients exposed to Marinol have found it to have less medical value than phytocannabis. Differences in the isomeric configuration between the native and synthetic versions are

thought responsible for the synthetic's lack of efficacy. Due to activists obtaining court orders, the US government has been obliged to supply plant cannabis to several registered medical cannabis patients since 1976, using cannabis grown at the University of Mississippi, for the treatment of glaucoma and other conditions unresponsive to conventional therapy.

5. G.W. Pharmaceuticals, a British company specialising in the investigation and production of cannabis based medicine has produced Sativex, a standardised whole plant extract of cannabis, available for clinical trials with varying ratios of THC and CBD (cannabidiol). Many thousands of patients have received Sativex, principally for the treatment of multiple sclerosis associated spasticity. Side effects have been few and easily managed. It is noteworthy that having treated over 5000 patients for several years no incidence of psychosis has been seen. Sativex is available for patients in Australia under a special access scheme, although the uptake has been restricted due to the high cost of Sativex and the regulatory burdens associated with its prescription. Many medical cannabis patients find it easier and better to access "black market" cannabis, to better exploit the subtle therapeutic differences between cultivars (cultivated varieties), probably due to the differing cannabinoid profile and perhaps differing terpene content.

6. As quoted by Justice Young, cannabis has been shown to be amongst the safest of all therapeutically active substances. In pharmacology, a measure of toxicity is the LD50. This is the dose of a substance, generally expressed as a ratio of the usual ingested dose to the dose required to kill 50% of the test subjects. For example alcohol has an LD50 between 5 and 10. The LD50 for cannabis has never been determined but is estimated to be in the order of 1:40,000. This is unique amongst pharmacologically active substances. Despite widespread use by many millions of people not a single death has been attributed directly to the pharmacological effects of cannabis. Further, unlike alcohol and tobacco, no organ associated damage has been attributed to cannabis.

7. Research has shown that even very heavy, long-term cannabis users who had smoked more than 22,000 joints over a lifetime seemed to have no greater risk of lung cancer than infrequent users or nonusers. These findings surprised the study's researchers, who expected to see an increase in cancer among

people who smoked cannabis regularly in their youth. "We know that there are as many carcinogens in cannabis smoke as in cigarettes," researcher Donald Tashkin, MD, of UCLA's David Geffen School of Medicine explained. "But we did not find any evidence for an increase in cancer risk for even heavy cannabis use."

8. The explanation lies in the fact that many of the cannabinoids posses some degree of anti-neoplastic activity, especially CBD, THC and CBG in that order. Unlike conventional chemotherapy, which uses toxic chemicals that are essentially non-specific and poison all dividing cells, the cannabinoids induce programmed cell death specifically in neoplastic cells by the process of apoptosis. Cell culture and animal experiments have verified the specific and therapeutically useful induction of apoptosis in tumour cells. All cannabinoids have zero cell toxicity. Indeed, military medical research in Israel has shown that THC and CBD are intracellular antioxidants and can protect watershed neural tissue after stroke or trauma and reduce any subsequent neurological deficit.

9. There are numerous anecdotal reports of the use of concentrated cannabis extracts in the treatment of advanced cancer, including well documented cures of previously intractable conditions. Medical cannabis is gaining acceptance overseas. Dr. William Courtney told HuffPost Live host Alyona Minkovski he was "quite a sceptic 5 or 6 years ago". Dr. Courtney continued that "my youngest patient is 8 months old, and had a very massive centrally located inoperable brain tumour. The child's father pushed for non-traditional treatment utilizing cannabis. They were putting cannabis oil on the baby's pacifier twice a day, increasing the dose... and within two months there was a dramatic reduction, enough that the paediatric oncologist agreed to not pursue traditional therapy. The tumour was remarkably reduced after eight months of treatment." Dr Courtney pointed out that the success of the cannabis approach means that "this child, because of that, is not going to have the long-term side effects that would come from a very high dose of chemotherapy or radiation... currently the child's being called a miracle baby, and I would have to agree that this is the perfect response that we should be insisting on frontline therapy for all children before they launch off on any medications that have horrific long term side effects such as chemotherapy."

10. The honourable members would be aware that this is not the first inquiry to be conducted in Australia concerning cannabis and that vis a vis the rest of the world we are backward and unenlightened in our approach to cannabis generally. The recent voting in the United States has established large scale medical cannabis access schemes in 18 states and legal recreational access in Colorado and Washington. Israel, Spain and many European countries run compassionate and investigative medical programs. In 2003 the then premier Carr promised a compassionate access scheme:- "The working group found that law-abiding people had been forced to turn to the black market to ease their pain. No decent government can stand by while fellow Australians suffer like that, while decent, ordinary people feel like criminals for simply medicating themselves." The president of the NSW branch of the Australian Medical Association, Dr Choong-Siew Yong, said it supported the trial. He said there was strong anecdotal evidence that cannabis eased the symptoms of sufferers of the diseases listed and could be more effective than drugs now available. The promised office of medical cannabis has yet to eventuate, more than a decade later.

11. When it comes to cannabis science Australia is about as advanced as was the Inquisition in its dealings with Galileo and his heliocentric theories. Australia is the only country on Earth that does not allow hemp seed as a human food. Hemp seed products such as hulled seed, non-dairy milks and ice creams and a host of other products are found on the supermarket shelves of Europe and North America and have been for years without problems. FSANZ has twice assessed the nutritional and food safety aspects of hemp seed with application A360 in 2002 and currently A1039 and found it to be safe and highly nutritious. This application has been stalled for several years by the spurious argument that it is not consistent with our international treaty obligations and may cause false positive results on saliva testing, a methodology discredited overseas but applied here for the pecuniary interests of certain police staff. Corrupt police and newspapers in the 1930's initiated the cannabis prohibition. It is deeply disturbing that the same elements are still active today. Indeed, the hysterical ramblings of the Murdoch press are often near verbatim to the Hearst press of the 1930's while drug related police corruption is as rife as ever. It could be said that the state of NSW has not evolved morally since the rum corp days.

12. The preferred option for cannabis law reform would involve the complete repeal of the cannabis prohibition and only enough regulation to ensure safe conduct in public and protection of minors. Production would be by a mix of private growing, proxy cultivation and licensed commercial cultivation. While our politicians evolve towards this distant ideal there is an urgent need for a workable system that could be quickly initiated and in an expeditious manner provide therapeutic cannabis for those with life threatening conditions. The proposal is as follows:- The Industrial Hemp Act of 2008 has paved the way for the establishment of industrial hemp crops around the state. To qualify as industrial hemp the mature inflorescences must have less than 1% THC and generally a CBD/THC greater than unity. Thus, they are an ideal source from which to extract CBD rich hemp oil, preferably by a solvent free method such as supercritical carbon dioxide or similar. Such processes are commercially available. The extracted oil would then be assayed for potency and encapsulated for administration. It is proposed that the first trial be conducted for patients diagnosed with astrocytoma grade 4 and be conducted at a major centre, such as Royal North Shore. Oncologists have been approached and are supportive of the proposal. The patients would be offered cannabis mono-therapy, conventional mono-therapy or combined chemotherapy and cannabis. Due to the generally rapid deterioration of astrocytoma patients, with death occurring generally between 1 and 2 years from diagnosis, any benefit would be seen relatively quickly, compared with more slowly growing tumours. In addition to the unique safety profile of the cannabinoids, CBD rich hemp extract provides additional benefit. It is well established that CBD significantly moderates the psychotropic effect of THC, allowing for much more robust dosing than would be possible with THC dominant therapy. Additionally, CBD and THC appear to act synergistically and via somewhat different pathways, again a significant therapeutic advantage.

13. The legislative and/or regulatory change required to establish this program is minimal, as hemp cultivation is already controlled under current legislation. The initial medical cannabis trial could be conducted under section 23(4)(b) of the NSW Misuse of Drugs Act, which permits the use of otherwise prohibited plants for scientific research and analysis. Such permits are issued by the chief health officer. In the alternative, the Industrial Hemp Act

could be modified to facilitate the collection and extraction of the inflorescences.

14. It has already been mentioned that NSW and Australia lag seriously behind the rest of the world when it comes to medical cannabis. Here is an opportunity for the legislators of NSW to move forward and finally provide a safe and effective plant based therapy for those with life threatening illness. I trust that you will give this matter your most sincere consideration. Although this submission is focussed narrowly on the investigational use of CBD rich hemp extracts for the treatment of intractable neoplasm, there is a multiplicity of other areas in which cannabis therapeutics would represent a significant advance in patient well being. The cannabis tincture produced and distributed by Mr Tony Bower deserves special mention. Kindly provided by Mr Bower without charge, the author has utilised this tincture in the management of a number of medical conditions, particularly chronic pain and found it to be safe and effective. In the management of chronic pain the deployment of cannabis tincture has allowed dramatic reduction in the dose of morphine needed, often to less than half what was previously required, with better symptom control and remarkably less side effects of nausea, constipation and confusion. The spasticity associated with spinal injury and neuropathic pain are other areas where cannabis therapeutics excels in safety and efficacy over current allopathic nostrums.

15. It is the author's opinion that the provision of medical cannabis should proceed along two independent pathways. The proposal outlined above for the management of astrocytoma deploys conventional allopathic methodology and will help to generate the data needed to move cannabis therapeutics into the mainstream. However, cannabis is also a herbal product and there are no practical or philosophical reasons why allopathic doctors, who for the most part have resisted the introduction of cannabis therapeutics for reasons of ignorance or self-interest, should have a controlling role in its future use. Cannabis can be used safely and effectively without rigid dose determination as practical experience has demonstrated that the patients themselves are the best ones to titrate the dose for maximum effectiveness and tolerability. Governments, especially corrupt governments and their police agencies should have no role in restricting private access to home grown cannabis, which can be easily and effectively ingested orally or via vapourisation.

16. This submission has been presented in an informal manner and without references. However, all material is true and accurate to the best of my knowledge and would be repeated under oath if required. Additionally, if substantiating evidence is required regarding any of the assertions made in this submission, they will be provided on request. Further, I undertake to appear in person and provide any additional information as may be required by the committee to facilitate this important and long overdue initiative.

Sincerely,
Dr Andrew Katelaris MD